In the Claims

1 (currently amended). A method for purifying recombinant human follicle stimulating hormone (FSH) or an FSH variant comprising the steps of subjecting FSH to:

(1) ion exchange chromatography at a pH of about 8.5;

(2) immobilised metal ion chromatography at a pH of about 9 ; and

(3) hydrophobic interaction chromatography (HIC) at a pH of about 8.25.

2 (original). The method of claim 1, wherein the ion exchange chromatography is carried out with a strong anion exchange resin.

3 (currently amended). The method of claim 2, wherein the anion exchange resin is a quaternary ammonium chromatography resin~~Q Sepharose FF, or a resin having similar properties~~.

4 (previously presented). The method of claim 1, wherein the ion exchange chromatography is carried out using borate buffer as eluent.

5 (original). The method of claim 4, wherein the borate buffer is at a pH of at or about 8.5.

6 (previously presented). The method of claim 1, wherein the immobilised metal ion chromatography is carried out with a resin having tridentate chelating groups.

7 (original). The method of claim 6, wherein the chelating groups are iminodiacetic acid.

8 (canceled).

9 (previously presented). The method of claim 1, wherein the immobilised metal ion chromatography is carried out with a metal ion selected from Cu^{2+} , Zn^{2+} , Ni^{2+} , Ca^{2+}, Mg^{2+} and Co^{2+}.

10 (previously presented). The method of claim 1, wherein the immobilised metal ion chromatography is carried out with Cu^{2+}.

11 (previously presented). The method of claim 1, wherein the immobilised metal ion chromatography is carried out using ammonium acetate as eluent.

12 (original). The method of claim 11, wherein the ammonium acetate buffer has a pH ~~of~~ at or about 9.

13 (currently amended). The method of claim 1, wherein the hydrophobic interaction chromatography (HIC) is carried out using chromatography resin comprising phenyl groups~~Phenyl Sepharose FF HS, or a resin having similar characteristics~~.

14 (previously presented). The method of claim 1, wherein the hydrophobic interaction chromatography is carried out using ammonium acetate (50 mM) /ammonium sulphate (0.25 M) as eluent.

15 (currently amended). A method for purifying recombinant human follicle stimulating hormone (FSH) or an FSH variant comprising the steps of subjecting FSH to:

(1) ion exchange chromatography;

(2) immobilised metal ion chromatography;

(2a) ion exchange chromatography; and

(3) hydrophobic interaction chromatography (HIC)~~The method of claim 1, comprising a second step of ion exchange chromatography (2a)~~, wherein a second step of ion exchange

chromatography (2a) is carried out after the step of immobilised metal ion chromatography, and before the step of hydrophobic interaction chromatography (HIC).

16 (original). The method of claim 15, wherein the second step of ion exchange chromatography is carried out using a weak anion exchange resin.

17 (currently amended). The method of claim 16, wherein the weak anion exchange resin comprises diethylaminoethyl groups~~is DEAE Sepharose FF resin, or a resin having similar properties~~.

18 (previously presented). The method of claim 1, further comprising a step of reverse phase chromatography (4), carried out after the step of hydrophobic interaction chromatography (HIC).

19 (canceled).

20 (currently amended). The method of ~~claim 19~~ claim 18, wherein the reverse phase chromatography is carried out using a solution comprising ammonium acetate (50 mM, pH at or about 7.6) with 20% (v/v) 2-propanol.

21 (previously presented). The method of claim 18, comprising a step of ultrafiltration (5), carried out after the step of reverse phase chromatography.

22 (currently amended). A method for purifying human recombinant ~~FSH~~ follicle stimulating hormone (FSH) comprising the steps of subjecting FSH to:

(i) ultrafiltration;

(ii) anion exchange chromatography on ~~Q Sepharose FF~~a resin comprising quaternary ammonium groups with a solution comprising ~~at or~~ about 50 mM borate, ~~at or~~ about 0.13 M NaCl, ~~pH at or~~ at a pH of about 8.5 as eluent;

(iii) subjecting the eluate of step (ii) to a step of immobilised metal ion affinity chromatography on ~~chelating Sepharose ff~~FF a resin comprising tridentate chelate groups, with Cu^{++} as metal ion, ~~and at or~~ with an solution of about 0.75 M ammonium acetate ~~pH at or about 9~~ at a pH of about 9 as eluent;

(iv) subjecting the eluate of step (iii) to a step of anion exchange chromatography on a resin comprising diethyldiaminoethyl groups~~DEAE Sepharose FF~~, with a solution comprising ~~at or~~ about 0.11 M Ammonium acetate, ~~pH at or~~ pH of about 8.5 as eluent;

(v) subjecting the eluate of step (iv) to a step of hydrophobic interaction chromatography on a chromatography resin comprising phenyl groups~~Phenyl Sepharose FF HS~~ with ~~at or~~ a solution comprising about 50 mM ammonium acetate, ~~at or~~ about 0.25 M ammonium sulphate, at a pH of ~~pH at or~~ about 8.25 as eluent;

(vi) subjecting the eluate of step (v) to a step of reverse phase chromatography on a reverse phase chromatography resin~~Source 30 RPC~~, with ~~at or~~ a solution comprising about 50 mM ammonium acetate, pH of about~~at or about~~ 7.6, and ~~with at or~~ about 20% of 2-propanol (v/v);

(vii) subjecting the eluate of step (vi) to a step of ultrafiltration; and

(viii) subjecting the retentate of step (vii) to a step of nanofiltration.

23-24 (canceled).

25 (withdrawn-currently amended). A composition of matter comprising:

(a) a purified recombinant human ~~FSH~~ follicle stimulating hormone (FSH) or FSH variant produced by the process of claim 1; or

(b) a composition comprising a purified recombinant human FSH or FSH variant produced by the process of claim 1 and a liquid.

26 (withdrawn-previously presented). The composition of matter of claim 25, wherein said liquid is a buffer, stabilizer or an excipient.

27 (new). The method of claim 1, comprising a second step of ion exchange chromatography (2a), carried out after the step of immobilised metal ion chromatography, and before the step of hydrophobic interaction chromatography (HIC).

28 (new). The method of claim 27, wherein the second step of ion exchange chromatography is carried out using a weak anion exchange resin.

29 (new). The method of claim 28, wherein the weak anion exchange resin comprises diethylaminoethyl groups.